



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/471,510	12/23/99	DIAB	MASIMO-145A

020995 QM12/0702
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EXAMINER
KREMER, M

ART UNIT	PAPER NUMBER
3736	5

DATE MAILED: 07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/471,510

Applicant(s)

DIAB, MOHAMED K.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. The preamble of claim 13 describes a method of claim 13. The preamble of claim 14 describes a method of claim 14. During the prior art examination, the preamble of claims 13-14 are considered to describe the method of claim 12. The preamble of claim 17 describes a method of claim 17. During the prior art examination, the preamble of claim 17 is considered to describe the method of claim 16.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-7, and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,295,471 to Kaspari. Kaspari discloses a processor in Fig. 3 and describes a process where signals generated by a transducer are converted from

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analog to digital signals and stored for analysis as stated in column 2, lines 35-59.

Various techniques are utilized during analysis to ensure the validity of the data and to eliminate artifacts. In column 5, line 41 to column 6, line 45 and Fig. 6, Kaspari teaches waveforms which are heartbeats which comprise a plurality of pulses. In column 8, line 21 to column 11, lines 25, Kaspari discloses the method of validating data and eliminating artifacts. In regard to claims 2-3 and 13-14, Kaspari teaches that the average period between beats can be determined by totaling the elapsed time between the first and last pulses and dividing by the total number of pulses. In regard to claim 5-6, the significant characteristics of each pulse include the time where the pulse initially exceeds the threshold, the time where the pulse reaches the peak, the amplitude of the peak, and the time where the pulse falls below the threshold (column 9, lines 10-16). In regard to claim 7, the processor uses a noise threshold to determine valid peaks (column 8, lines 41-55). In regard to claim 10, Kaspari discloses that a time window has been empirically established for pulses above certain thresholds to be valid (column 10, lines 31-39). In regard to 11, Kaspari teaches that pulses are excluded when they do not meet the minimum/maximum time criteria and the reference level which is based on an average of the four largest amplitudes (column 10, lines 51-66).

5. Claims 1, 4-7, 9-12, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,274,548 to Bernard et al. Bernard et al. discloses a method and apparatus for segmenting and classifying pulsed signals in medical applications as stated in column 2, lines 6-23. In column 1, lines 13-17, Bernard et al.

states that the method may be equally applied to a noised pulse signal. In column 4, lines 13-17, Bernard et al. teaches that heartbeats can be segmented in the method. Fig 2 shows a portion of a recorded pulse signal with multiple pulses. In regard to claim 4, the method of Benard et al. teaches the method of segmenting the pulse signals into triangular forms as disclosed in column 2, line 60 to column 3, line 56. In regard to claims 5-7, the segmentation defines a set of pulses which are characterized by their start, end, and peak (column 4, lines 9-10). For classification, each pulse is quantitatively defined by parameters including average amplitude of pulse (claim 7) and average of the slopes of the pulse rise and fall fronts (claim 9) as stated in column 4, lines 18-31. The segmentation and classification allow pulses to be grouped together which inherently excludes other pulses.

6. Claims 1, 5-10, 12-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,365,934 to Leon et al. Leon et al. discloses a method and apparatus for measuring the heart rate using an autocorrelator. In column 2, lines 3-24, the autocorrelator periodically generates an autocorrelation signal of the input signal over a predetermined time period. The signal indication logic which is responsive to the autocorrelation detects a periodic signal in the autocorrelation signal and generates a heart rate signal corresponding to the frequency of the periodic signal. In column 14, line 31 to column 15, line 17, Leon et al. teaches that when using stair climbers and treadmills, it is difficult to isolate the user's heart rate. Leon et al. discloses an alternative technique for detecting the indications of the periodic signals in the

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autocorrelation output which is illustrated in Fig. 16. The digital signal processor filters the autocorrelation output for the indications of periodic signals in accordance with a plurality of filter criteria. These filter criteria reduce the autocorrelation signal to a plurality of candidate signals. The digital signal processor stores the candidate signals in a candidate array, in which each candidate signal is represented by its peak-to-trough pulse height and its frequency (as expressed in beats per minute). The candidate signals are sorted in descending order of frequency. The digital signal processor 44 then performs an arbitration function to select one of the candidate heart rate signals generated by the signal indication operation. The filtering criteria include pulse height greater than a threshold value (claim 7), pulse width which inherently includes pulse period (claim 6), pulse shape that is a local peak between two local minimums (claim 9), and a pulse that is substantially vertically symmetrical (claim 8). In regard to claim 10, a candidate heart rate is rejected if it is outside a predetermined range (column 16, lines 30-40).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,553,615 to Carim et al. discloses a method and apparatus for noninvasive prediction of hematocrit which includes an adaptive peak and valley detector for waveforms generated in photoplethysmography and a method for estimating the confidence level of photoplethysmographic signals.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Examiner
Art Unit 3736
June 26, 2001



ERIC F. WINAKUR
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.